DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

February 21, 2002

**WARNING LETTER**
**CHI-15-02**

**CERTIFIED MAIL**
**RETURN RECEIPT REQUESTED**

Mr. Daniel E. Hugo, President
Greenville Livestock Inc.
25815 Hugo Rd.
Centralia, IL 62801

Dear Mr. Hugo:

An investigation of your cattle grower/dealer operation conducted January 18 - 25, 2002, found that a beef steer from your establishment was offered for sale for slaughter as human food in violation of Section 402(a)(2)(C)(ii) of the Federal Food, Drug, and Cosmetic Act (Act).

On December 3, 2001, a steer was sold for slaughter as human food to [redacted], [redacted]. USDA analysis of tissue samples collected from that animal identified the presence of 13.32 parts per million (ppm) Tilmicosin in the liver tissue; 06.69 ppm in the muscle tissue; and 19.86 ppm in the kidney tissue. The established regulatory action level for Tilmicosin in the liver tissue of cattle is 1.2 ppm (Title 21, Code of Federal Regulations, Part 556.735). There is no tolerance for the drug in muscle or kidney tissue. The presence of this drug in the edible tissue from this animal causes the food to be adulterated under the Act.

Our investigations also found that you hold animals under conditions which are inadequate in that medicated animals bearing potentially harmful drug residues are likely to enter the food supply. You lack an adequate system for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues from edible tissue. You need to implement a system in which to record and maintain permanent drug treatment records that will adequately identify and/or segregate drug treated animals.

The above is not intended as an all-inclusive list of violations. As a producer of animals offered for human consumption, you are responsible for assuring that your overall operation and the food products you produce for distribution are in compliance with the law.

You should take prompt action to correct the violation, and you should establish procedures whereby such violation does not recur. Failure to promptly correct the violation may result in regulatory action without further notice, such as seizure and/or injunction. This letter constitutes notification under the law.

Please advise this office in writing within 15 working days of receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Richard Harrison, Director, Compliance Branch.

Sincerely,

\s\
Edward W. Thomas
Acting District Director